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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,638	12/15/2003	Philippe Rouanet	029488-0113	9056

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,638	ROUANET ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39 and 43-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/2008 has been entered. It is noted that in the previous Notice of Allowance, claims 31-36 and 38 were cancelled. Currently claims 39 and 43-48 are under examination.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39, 43-48 rejected under 35 U.S.C. 102(e) as being anticipated by Bua (US Pg/Pub 2004/0138314).

Bua teaches compositions for percutaneous administration that comprise 4-hydroxy tamoxifen as the sole active agent, isopropyl myristate, ethyl alcohol,

hydroxypropylcellulose and a phosphate buffer. Table 1 outlines this composition and gives amounts that fall within that of the presently claimed invention, in particular 4-hydroxytamoxifen is present at 0.02 g, ethyl alcohol is present at 72 g, isopropyl myristate is present at 1 g, hydroxypropylcellulose 1.5 g and the rest phosphate buffer. This composition falls within the percentage ranges currently claimed in claims 39, 43-47. Bua teaches that the 4-hydroxytamoxifen is packaged in a dose-meter pump, meeting the limitation of claim 48.

Claims 39 and 43-48 rejected under 35 U.S.C. 102(e) as being anticipated by de Lignieres et al. (US Pg/Pub 2005/0032909).

De Lignieres et al. teach compositions for percutaneous administration that comprise 4-hydroxy tamoxifen as the sole active agent, isopropyl myristate, ethyl alcohol, hydroxypropylcellulose and a phosphate buffer. Table 1 outlines this composition and gives amounts that fall within that of the presently claimed invention, in particular 4-hydroxytamoxifen is present at 0.02 g, ethyl alcohol is present at 72 g, isopropyl myristate is present at 1 g, hydroxypropylcellulose 1.5 g and the rest phosphate buffer. This composition falls within the percentage ranges currently claimed in claims 39, 43-47. Bua teaches that the 4-hydroxytamoxifen is packaged in a dose-meter pump (paragraph 0047), meeting the limitation of claim 48.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39, 43, 45-47 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11-12 and 23-24 of copending Application No. 10/734,644. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a pharmaceutical composition comprised of 4-hydroxy tamoxifen, isopropyl myristate, alcohol, an aqueous vehicle and a gelling agent in particular amounts. The claims of Application 10/734,644 are drawn to a method of reducing breast density in a patient comprising administration of a composition comprising 4-hydroxytamoxifen, isopropyl myristate, an alcohol and a gelling agent, which broadly reads on the present composition. As there was no restriction between this particular claimed method and the composition in the present application, a double-patenting rejection is warranted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 39, 43-48 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-13, 15-23 of copending Application No. 11/009,390. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a pharmaceutical composition comprised of 4-hydroxy tamoxifen, isopropyl myristate, alcohol, an aqueous vehicle and a gelling agent in particular amounts. The claims of Application 11/009,390 are drawn to a method of treating a male patient comprising percutaneous administration of 4-hydroxy tamoxifen, isopropyl myristate, ethyl alcohol and hydroxymethylcellulose in amounts that overlap with those presently claimed. As there was no restriction between this particular claimed method and the composition in the present application, a double-patenting rejection is warranted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 39 and 43-48 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-9, 11-12, 15-20 and 22 of copending Application No. 10/805,528. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a pharmaceutical omposition comprised of 4-hydroxy tamoxifen, isopropyl myristate, alcohol, an aqueous vehicle and a gelling agent in particular amounts. The claims of Application 10/805,528 are drawn to a method of treatment

comprising percutaneous administration of 4-hydroxytamoxifen with isopropyl myristate, ethanol, hydroxypropylcellulose and a phosphate buffer in amounts with those presently claimed. As there was no restriction between this particular claimed method and the composition in the present application, a double-patenting rejection is warranted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 39 and 43-48 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-10 of copending Application No. 10/734,640. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a pharmaceutical composition comprised of 4-hydroxy tamoxifen, isopropyl myristate, alcohol, an aqueous vehicle and a gelling agent in particular amounts. The claims of Application 10/734,640 are drawn to a method of treatment for mastalgia comprising percutaneous administration of 4-hydroxy tamoxifen with isopropyl myristate, ethyl alcohol and hydroxypropylcellulose. As there was no restriction between this particular claimed method and the composition in the present application, a double-patenting rejection is warranted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 39 and 43-48 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-11 of copending Application No. 11/249,122. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a pharmaceutical composition comprised of 4-hydroxy tamoxifen, isopropyl myristate, alcohol, an aqueous vehicle and a gelling agent in particular amounts. The claims of Application 11/249,122 are also drawn to a pharmaceutical composition comprising 4-hydroxy tamoxifen, isopropyl myristate, alcohol, an aqueous vehicle and a gelling agent in amounts that differ but overlap with that of the present invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617